CHARTER DOD PHARMACY AND THERAPEUTICS COMMITTEE

I. AUTHORITY

The National Defense Authorization Act for Fiscal Year 2000, Public law 106-65, Oct. 5, 1999, section 701, amended chapter 55 of title 10, United States Code, by inserting after section 1074f a new section, 1074g, entitled Pharmacy benefits program. Under section 1074g(b), the Secretary of Defense was required to establish a Pharmacy and Therapeutics Committee for the purpose of developing a uniform formulary of pharmaceutical agents, reviewing such formulary on a periodic basis, and making additional recommendations regarding the formulary as the committee determines necessary and appropriate. The committee functions under procedures established by the Secretary under regulations promulgated to implement this section.

II. Dod Pharmacy and Therapeutics Committee

A. GENERAL PROVISIONS

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee (henceforth, P&T Committee) is responsible for development and maintenance of a uniform formulary. It consists of government and non-government members whose objective is to encourage the use of safe, effective pharmaceutical agents that will produce the desired outcomes of drug therapy at a reasonable cost to DoD. The DoD P&T Executive Council is a separate committee composed solely of federal employees. The Executive Council is responsible for performing certain inherently governmental functions relevant to a pharmacy benefits program and providing other direction and assistance to the P&T Committee.

B. PROCEDURES

The uniform formulary shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes. The selection for inclusion on the uniform formulary of particular pharmaceutical agents shall be based on the relative clinical effectiveness and cost effectiveness of the agents in each therapeutic class of pharmaceutical agents.

- 1. Clinical Effectiveness: The P&T Committee shall presume a pharmaceutical agent is included in a therapeutic class of the uniform formulary. This presumption shall exist unless the P&T Committee finds by majority vote that the agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other drugs included on the uniform formulary in that therapeutic class. If the P&T Committee makes such finding, the P&T Committee may recommend that the pharmaceutical agent be excluded from a therapeutic class of the uniform formulary.
- 2. Cost Effectiveness: The P&T Committee, in evaluating the cost effectiveness of pharmaceutical agents, shall evaluate the cost of agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of such agents. If the P&T Committee determines by majority vote that a pharmaceutical agent in a therapeutic class is not cost effective in relation to

the safety, effectiveness, and clinical outcome of such agent, the P&T Committee may recommend that the agent be excluded from the therapeutic class of the uniform formulary. The approving authority shall rely on the evaluation by the P&T Committee as it relates to cost effectiveness.

- 3. Basic Core Formulary: The Basic Core Formulary (BCF) is a sub-set of the approved uniform formulary and applies only to Military Treatment Facilities (MTFs). The Basic Core Formulary is the minimum formulary that must be available at all MTFs. Pharmaceutical agents recommended for approval for the uniform formulary may also be recommended for inclusion or exclusion on the Basic Core Formulary.
- 4. All recommendations shall be by majority vote of the voting members, unless otherwise described in this charter.

C. <u>DUTIES OF THE DoD PHARMACY AND THERAPEUTICS COMMITTEE</u>

- 1. Consider the relative safety, effectiveness, cost, and other pertinent factors in deciding which pharmaceutical agents are included on the uniform formulary and BCF.
- 2. Conduct therapeutic drug class reviews on a scheduled basis. The schedule for class reviews will be published on the PEC web site.
- 3. Evaluate requests for changes to the uniform formulary and the BCF from within the Military Health System (MHS). The P&T Committee will develop a standard format and procedure for submission of requests.

D. <u>DUTIES OF THE P&T EXECUTIVE COUNCIL (General and inherently Governmental)</u>

- 1. Review Military Health System pharmacy utilization and cost data.
- 2. Consider Medical Readiness implications pertaining to BCF issues.
- 3. Review and approve the contracting strategies and evaluation factors for DoD and joint VA/DoD pharmaceutical procurement contracting initiatives. The Executive Council will also prospectively identify circumstances where it would be medically necessary to use a non-contracted drug in lieu of a contracted drug.
 - 4. Monitor the effectiveness of the MHS drug distribution system.
- 5. Identify drugs that are candidates for prior authorization and recommend prior authorization criteria that would be applied across the MHS.
- 6. Consider the relative safety, effectiveness, cost, and other pertinent factors in deciding which pharmaceutical agents are included on the BCF and recommend to the P&T Committee for inclusion on the Uniform Formulary.

- 7. Conduct therapeutic drug class reviews on a scheduled basis. The schedule for class reviews will be published on the PEC web site.
- 8. Evaluate requests for changes to the uniform formulary and the BCF from within the Military Health System (MHS). The Executive Council will develop a standard format and procedure for submission of requests.

E. MEMBERS

The P&T Committee members must have expertise in identifying the medical and pharmaceutical needs of the populations served throughout the Military Health System (MHS). The P&T Committee will have 22 voting members and additional non-voting members as outlined below. Those members who are military and civilian personnel of the Department of Defense shall also be members of the Executive Council. A physician nominated by the Surgeons General and selected by the Director, TRICARE Management Activity will chair the P&T Committee.

1. Voting Members:

- a. Physician Chairman.
- b. Director, DoD Pharmacoeconomic Center (PEC) (recorder).
- c. The Army, Navy and Air Force Surgeon General (SG) Internal Medicine specialty consultants or designees.*
 - d. One Army, Navy or Air Force SG Pediatric specialty consultant* or designee.
- e. One Army, Navy or Air Force SG Family Practice specialty consultant* or designee.
- f. One Army, Navy or Air Force SG Obstetric/Gynecology specialty consultant* or designee.
 - g. Two TRICARE network providers.**
 - h. One Uniformed Services Family Health Plan (USFHP) physician*** or designee.
- i. The Army, Navy, and Air Force Pharmacy specialty consultants or designated representatives.
- j. The Defense Supply Center Philadelphia (DSCP) Contracting Officer's Technical Representative (COTR) for the NMOP program.
 - k. One pharmacist representing the contractor responsible for the NMOP.

- l. One pharmacy director from each TRICARE Managed Care Support Contractor (MCSC).
 - m. One physician or pharmacist from the Department of Veterans Affairs (DVA).
- * The Pediatric, Family Practice and Obstetric/Gynecology positions on the P&T Committee will

be rotated among the Services every 3 years.

- ** Providers will be selected by the Chairman, after nomination by the Managed Care Support Contractors.
- *** Selected by USFHP.
 - 2. Non-Voting Members:
- a. One physician representing the Office of the Assistant Secretary of Defense (Health Affairs).
 - b. One USFHP Administrator.
 - c. Director, DoD Pharmacy Programs, TRICARE Management Activity (TMA).
 - d. One physician or pharmacist from the United States Coast Guard.
- e. One physician or pharmacist from Joint Readiness Clinical Advisory Board (JRCAB).
 - f. One representative from the TMA Office of General Counsel.
- 3. Voting members should be available to serve on the P&T Committee for a minimum of two years, but may not serve on the P&T Committee for more than four years. The MCSC's representatives may serve for the duration of their respective contract period.
- 4. Additional subject matter experts from the military services may be requested to participate as required to address specific drugs and/or therapeutic classes under review.
- 5. The DoD P&T Committee will meet at least quarterly as scheduled by the Chairman. Meetings will be scheduled far enough in advance to facilitate appropriate scheduling and notice of Formulary Beneficiary Advisory Panel (FBAP) meetings.
- 6. All members, voting and non-voting, and requested invitees, e.g. subject matter experts, will be funded for travel expenses by TMA.

F. COSTS

The estimated annual operating costs associated with supporting the P&T committee's functions are approximately \$250,000 per year, including all direct and indirect expenses. It is estimated that 1.0 FTE will be required to support the P&T Committee. Members will serve without compensation; however, travel, per diem and subsistence will be paid in accordance with the Joint Travel Regulations.

G. SUPPORTING AGENCY

The TRICARE Management Activity will provide a contractor for administrative and related support to the P&T Committee.

III. AGENDA & ROUTING OF MINUTES

The P&T Committee will establish a schedule for dissemination of the agenda and completion of the minutes.

IV. DURATION OF CHARTER:

The TMA Executive Director will review this charter biennially from the date of approval.

V. DATE CHARTER IS FILED: May 30, 2002